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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,449	04/13/2000	James Norris	9175-016-999	6716

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225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER

EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/548,449

Applicant(s)

NORRIS ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10, 11, 13-16, 18-24 and 30-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10, 11, 13-16, 18-24 and 30-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9-15-03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

2. Applicant's filing of a Terminal Disclaimer on 12-15-03 has overcome the Double Patenting rejection of claim 1 over claims 3-5 of US Patent No. 6,271,359. This rejection is therefore withdrawn. Additionally, the rejection of claim 30 for lack of enablement under 35 USC 112, 1st paragraph is withdrawn in response to Applicant's amendment to the claims filed on 12-15-03.

3. Claims 1-7, 10, 11, 13-16, 18-24 and 30-33 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the Official Action mailed 2-13-03.

4. Applicant's arguments filed 7-18-03 and 12-15-03 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds the specification as filed, and the prior art adequately describes the presently claimed subject matter. Applicants make reference to the specification as filed at page 13, lines 16-22 that list a variety of toxic gene products. In addition, Applicants cite Holcik & Iyer (1997), and GenBank as sources for information regarding genes encoding toxic gene products, and their corresponding nucleic acid sequences. Contrary to Applicant's assertions, it is noted that Applicant's references to the specification and Holcik & Iyer (1997), merely provide a description of commonly known toxic

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antibacterial agents. However, it is noted that the instant claims are not limited to only toxic agents encoding toxic gene products that are toxic antibacterial agents. The instant claims are broadly drawn to toxic agents effective against any and all organisms. In particular, the instant claims encompass any toxic agent that is: 1) a toxic gene product, including all polymorphic, allelic, and splice-variants of said gene product, including all mutated forms; 2) an antisense RNA, wherein the antisense RNA reduces the expression of an essential gene required for the survival of a cell, wherein the structures of said essential gene is unknown, and therefore the structure of the antisense RNA is also unknown; 3) a trans-acting ribozyme, wherein the trans-acting ribozyme reduces the expression of an essential gene required for the survival of a cell, wherein the structures of said essential gene is unknown, and therefore the structure of the binding arms of said trans-acting ribozyme is also unknown; 4) a sense RNA that reduces the activity of an essential antisense molecule, however since the structures of the antisense molecules are not defined the structures of the sense RNAs used as toxic agents are also undefined. The instant claims are also drawn to a broad genus of nucleic acid molecules encoding pathogen-specific, or tissue specific promoters, again, the scope of the claims reads on any particular class of pathogen, and any particular class of tissue. Although claim 16 lists a variety of pathogen-specific promoters, it is noted that each promoter listed are either specific for *Pseudomonas* or *Staphylococcus* bacteria. However, the instant claims are not limited to only bacteria-specific promoters. Additionally, the instant claims encompass generic virions comprising the nucleic acid molecules of the claimed invention encoding one or more toxic agents, wherein the virion has a reduced ability to transfer viral DNA, but is capable of transferring recombinant nucleic acid.

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Contrary to Applicant's assertions, the discussion of multiple forms of antibacterial gene products in the specification as filed, and as discussed in Holcik & Iyer (1997), does not provide an adequate description of other toxic agents that would be effective against organisms other than bacteria. See MPEP § 2163, which states, "[A] biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." In the instant case, Applicant's description of antibacterial toxic agents does not provide a direct correlation between the structures of the full scope of toxic agents encompassed by the instant claims and their corresponding function, such that one of skill in the art would be able to predict the structures of all other forms of toxic agents that are encompassed by the instant claims, in particular those agents that would be effective against pathogens other than bacteria, and function in a pathogen-specific manner or tissue-specific manner.

Therefore, the specification as filed does not convey with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. One of skill in the art, as of the filing date sought, at the time the would not have recognized that applicant was in possession of the full scope of toxic gene products, antisense RNA, trans-acting ribozymes, sense RNA, pathogen-specific or tissue-specific promoters, virions, or compositions thereof as encompassed by the instant claims.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Janet L. Epps-Ford, Ph.D.
Examiner
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JLE